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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,640	02/07/2001	Babak Nemati		4426

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Suzannah K Sundby
Jacobson Holman PLLC
400 Seventh Street NW
Washington, DC 20004-2201

EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,640

Applicant(s)

NEMATI, BABAK

Examiner

Michael J Hayes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 45-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not enabled the invention with respect to the means for bypassing, means for delivering a clarifying agent and means for delivery or collection of light in a single apparatus of light microscopy, confocal microscopy, optical coherence tomography, fluorescence spectroscopy, reflectance spectroscopy, non-invasive sensing, concentration measurements, photodynamic detection, iontophoresis, electroporation, acoustic generator, or means applying optical pressure, temperature gradient, concentration gradient, tape stripping, laser ablation, ultrasonic generation, radiofrequency

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generation, electrical generation, solvent penetration, microneedle array, or chemical enhancement.

Applicant's only description given is with a syringe needle with an optical fiber within the needle lumen. See fig. 6.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has failed to set forth in the specification an adequate disclosure showing what is meant by the language of claim 37 of means for bypassing, means for delivering an agent, and means for light delivery or collection all in a single apparatus. Applicant has not described the corresponding structure of the means for language in the claims. See MPEP §2181.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-56, 62, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINEZ (U. S. Patent No. 4,222,375). Martinez discloses an apparatus capable of enhancing the optical transparency of biological tissue comprising means for bypassing the surface barrier (needle), means for delivering clarifying agent (syringe), means for delivery of light (fiber optic cable). The various uses recited in the claims are readable on the prior art because the prior art is capable of performing these functions and supplying light for these

functions. The device disclosed by Martinez is used to deliver fluids and includes means for bypassing as the edge of the needle that is capable of abrading the surface permeability barrier. The rigidity of the needle allows the needle to pass through the surface barrier. Applicant discloses that abrading a tissue barrier causes minimal damage (claim 56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-52, 54-56, 62-64, 66, and 69 are rejected under 35 U.S.C. 103(a) as being obvious in view of CHAN et al. (6,275,726). Chan discloses means for bypassing the surface permeability barrier of tissue, means for delivering a clarifying agent, and means of light delivery for diagnostic and therapeutic applications (1:50-65; 2:24-32; 3:51-67; 4:1-12; 7:36-63; 8:37-40). The various skin appendages will inherently be affected when the agent is injected into the tissue. Chan does not disclose the various parts to be used in one apparatus; however, it is well within the knowledge of the skilled artisan to make that which comprises plural parts into one part to simplify the use of a device. The use of the porative means and delivery means simultaneously or sequentially is inherent. If not used simultaneously then they must be used sequentially (i.e., first one, then the other, in no particular order).

Claims 53, 57-59, 61, 65, 67, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINEZ as applied to claims 37 and 38 above, and further in view of

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EDWARDS (U. S. Patent No. 5,833,647). Martinez discloses the claimed invention except for bypassing means including iontophoresis system, electric pulse generator, acoustic generator, and temperature gradient. Edwards teaches using these methods which inherently require the appropriate systems and generators to drive molecules. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Edwards in the invention of Martinez in order to deliver the agent across the skin barrier. Both Edwards and Martinez are concerned with delivering agents across the surface permeability barrier.

Claims 60 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINEZ as applied to claim 37 above, and further in view of WEAVER (U. S. Patent No. 5,019,034). Martinez discloses the claimed invention except for bypassing means to apply optical pressure and penetrating solvent. Weaver teaches the use of means to apply optical pressure and penetrating solvent for transdermal delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to facilitate delivery of an agent across the skin barrier. Both Martinez and Weaver are concerned with delivering agents across the surface permeability barrier.

Response to Amendment

The Affidavit under 37 CFR 1.132 filed 11/12/03 is insufficient to overcome the rejection of claims 37-56, 62, and 69 based upon 35 USC 102 with respect to Martinez and of claims 37-52, 54-56, 62-64, 66, and 69 based upon 35 USC 103(a) with respect to Chan as set forth in the last Office action because: Martinez is capable of bypassing the tissue permeability barrier with minimal tissue damage because claim 56 now recites that abrading the barrier is minimal tissue

damage. Martinez has an edge of the needle that is capable of abrading the tissue barrier. Applicant's statements of disagreement with the obviousness determinations of previous office actions are noted, but not convincing. The above rejections are maintained with the discussions of obviousness given above. Applicant has given opinion in the affidavit, not facts.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EPPSTEIN (U. S. Patent No. 6,527,716) shows various devices for bypassing a surface permeability layer to deliver agents to covered biological tissues.

Interview

Applicant mentioned the possibility of an interview in his last response. If Applicant desires an interview he can reach the examiner at the number below to schedule a date and time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh
12 December 2003


MICHAEL J. HAYES
PRIMARY EXAMINER